STREAMLINED AND COST-EFFECTIVE FORMULATION DEVELOPMENT FOR DRY POWDER INHALERS

MVIC

www.mvic.se

Formulation Development (FD) for Dry Powder Inhaler (DPI) Products

MVIC offers streamlined, cost-effective and high-quality performed inhalation formulation development packages. Our offer extends to customers requiring cutting edge input for problem solving, as well as customers without resources to carry out a development program by themselves.

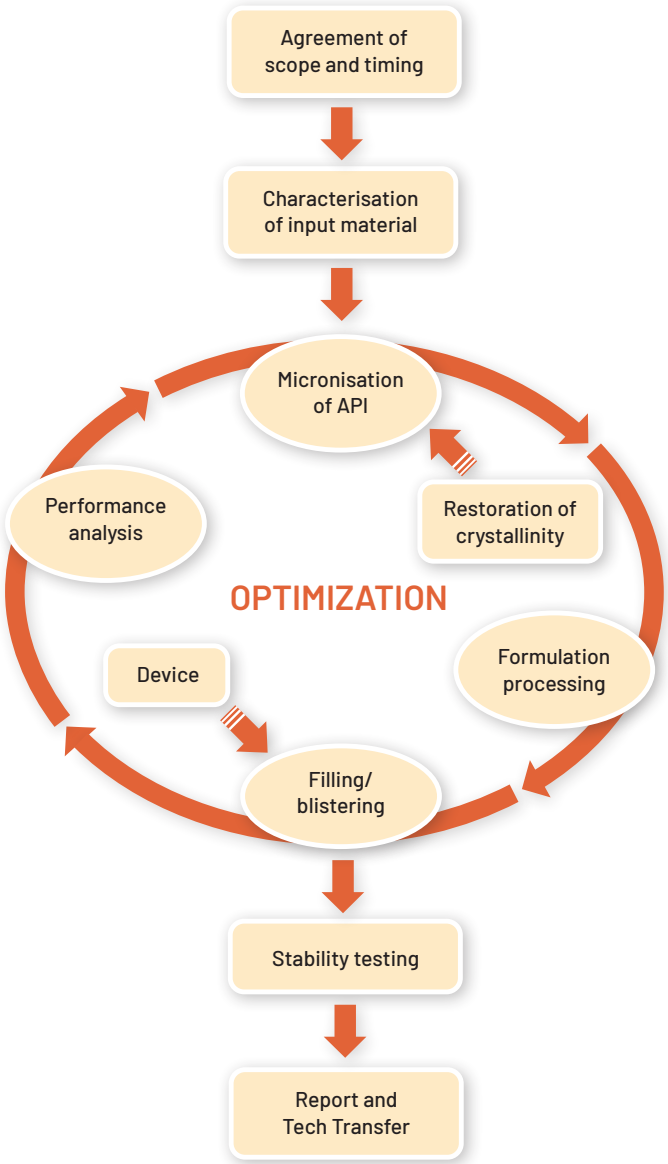
The extent and design of the development program is elaborated in collaboration with the customer. The combined experience from key MVIC companies allows us to lead and assist in all aspects of inhalation product development, from an early pre-clinical and medicinal chemistry phase via CMC with early development and scale-up to phase I and phase II.

For generic product development, MVIC has extensive experience in reverse engineering, being an important initial activity. Throughout the development, the regulatory landscape and requirements will be considered.

MVIC OFFERS ITS SERVICES AS A SINGLE COMPANY

- One CDA
- One proposal
- One supplier agreement
- One invoice
- One contact person
- One project manager
- One accountable supplier

EXAMPLE OF PROJECT WORK FLOW



Specialised MVIC Skills that are Integrated in the Development Program

SOLID STATE CHARACTERISATION

Fundamental characterisation of critical inherent and induced material properties all the way from raw material to the final processed formulations e.g.;

- Particle size distribution determination
- Visualisation using different microscopical techniques (E.g. SEM)
- Crystallinity and form assessment
- Thermal properties determination
- Humidity interaction characterisation
- Specific surface area determination
- Inherent and induced amorphicity detection
- Excipient compatibility evaluation

RESTORATION OF CRYSTALLINITY (CONDITIONING)

Material may have inherent amorphicity as received or obtain induced amorphicity from processing. In case the amorphicity is located on particle surfaces it is vital to control and/or restore the crystallinity.

- Detection and quantification of extremely small amount of amorphicity
- Development of tailor-made conditioning method used to restore surface crystallinity
- Actual conditioning of partly amorphous material in laboratory development scale
- Providing state of the art conditioning equipment suitable also in production environment

FORMULATION PROCESSING

Compounds intended for inhalation need to be processed with great care, using specialised equipment and environmental conditions (like controlled RH) and fulfilling harsh quality attributes.

- Laboratory scale fluidized jet mill capability including various internal surface options
- Homogeneous mixing of micron sized primary particles
- Intensive mixing of adhesive (ordered) mixtures with scale up options
- Filling capability (manual or semi-automated)
- Full analytical capability assessing e.g. content, homogeneity or degradation products
- Complete stability study facilities and capabilities including GMP manufacturing storage and analyses

INHALER TESTING

A genuine inhaler performance testing through the development process is vital so that the impact of formulation changes is monitored. This enables fulfilment of the project end points and prediction of outcome in e.g. BE PK studies.

- Delivered dose testing
- Aerodynamic particle size distribution testing, with the NGI impactor
- Performance at different inhalation air flows
- In vivo relevant in vitro testing, such as different anatomical throat sizes in combination with different patient air flow profiles.

PROJECT MANAGEMENT

New prerequisites, project objectives or revised business cases require a smooth and swift interaction between c ustomer and service provider.

- The dedicated MVIC FD project manager will engage in the initial design and scope of the program and will drive the project from start to finalisation. The project manager will coordinate the work within MVIC and will be one person contact for the customer.
- Knowledge transfer between MVIC and customer is performed continuously during the entire development program.

MVIC AB – YOUR PARTNER AND CRO FOR INHALATION PRODUCT DEVELOPMENT

When heading major inhalation development projects, there are three things that will qualify you for success.

The first is a very skilled project manager, i.e. yourself. The second and third are a full-fledged span of competence and a vast experience in inhalation technology. That´s us.

At MVIC we discuss strategic aspects of device and formulation development with our clients. Already at the first meeting we give professional aspects on how ideas and early development should be developed into inhalation products.

Working with us, you will often get straightforward answers to complex questions. You will be amazed.

Our project managers and specialists have worked in the outmost frontline of the world when it comes to inhalation technology.

Most of us also have a very sharp business approach from years in top management and vast experience in working with a wide range of small to large pharma clients in pharmaceutical development projects.

We are a CRO and Partner with more than 70 project managers and specialists in Discovery, Formulation, Regulatory, Device and Product Development.

We are located in Lund, a part of Southern Sweden with its cluster of universities, hospitals and pharmaceutical industries in Southern Scandinavia.

CONTACT

For contact and more information

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